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510 (k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: March 16, 2006

510(k) number: _____ MAY 15 2006

Applicant Information:

Cardima, Inc.

47266 Benicia Street

Fremont, CA 94538

Contact Person: Eric Chan, Ph.D.
Phone Number: (510) 354-0176
Fax Number: (510) 657-4476

Device Information:

Classification:	Class II
Trade Name:	Cardima Ablation System
Classification Name:	Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:

The subject device and accessory are substantially equivalent in intended use and/or method of operation to the Cardima Ablation System (K022008)

Intended Use:

The Cardima Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Device Description:

The Cardima Ablation System consists of the disposable Cardima Ablation Probe with Stabilization Sheath, the reusable INTELLITEMP® energy management device, and associated cables.

Test Results:

Performance

Results of in-vitro testing demonstrate that the Cardima Ablation System is safe and effective for its intended function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2008

Cardima, Inc.
c/o Eric Chan, Ph.D.
Vice President, Product Development
47266 Benicia Street
Fremont, CA 94538-73303

Re: K060715
Trade/Devices Name: Cardima Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: April 21, 2006
Received: April 21, 2006

Dear Dr. Chan:

This letter corrects our substantially equivalent letter of May 15, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

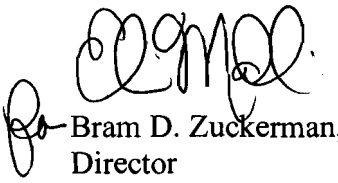
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060715

Indications for Use

510(k) Number (if known): _____

Device Name: Cardima Ablation System

Indications for Use:

The Cardima Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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